

TITLE OF INVENTION

REINFORCED MEDICAL PROBE COVER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

5 STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

1. Field of Invention

10 **[0003]** The present invention pertains to the field of medical probes. More particularly, the present invention is directed to a probe cover having reinforced layers for covering a medical probe prior to insertion into a sterile field.

2. Description of the Related Art

[0004] In the medical field, it is well know to use invasive probes for many
15 various applications. Typical medical probes include, but are mot limited to, endoscopes, ultra-sound probes, rectal or vaginal probes, esophageal probes, as well as surgical instruments. Such medical probes are manipulated from either a sterile or non-sterile field, with the insertion end of the probe disposed within a sterile field. In so placing the probe, it is necessary that the portion of the probe in
20 the sterile field be maintained as sterile. Accordingly, it is known in the art to provide a sheath or cover over the insertion end of probe prior to insertion into the sterile field. Application of the cover onto the probe is normally followed with application of an elastic gasket or a restraining band around one end of the cover to retain the cover thereon.

25 **[0005]** FIGS. 1 and 2 illustrate one device of the prior art. A sheath **10** for receipt on the end of an endoscope **40** or other medical probe is fabricated from a single layer of flexible material. Typically, the material is a medical grade plastic. The sheath **10** defines a tubular configuration defining a receiving end **12**

configured to receive a distal end **42** of the endoscope **40**. To this extent, an opening **14** is defined by the receiving end **12** for receiving the endoscope distal end **42**. A throat **16** is defined a selected distance from the receiving end **12**. The throat **16** is adapted to closely receive the endoscope distal end **42**. A sleeve
5 portion **18** is defined between the throat **16** and the distal end **20** of the sheath **10**.

[0006] A typical sheath **10** is fabricated from a single thickness of flexible plastic film, which, in one tested device, provides approximately 0.35 pounds of tensile strength. While this strength is capable of preventing puncture or other destruction of the sheath **10**, it is insufficient to retain the sheath **10** on the
10 endoscope **40** without assistance. Accordingly, a retainer **28** is provided to maintain the position of the sheath **10** on the endoscope **40** once positioned. The retainer **28** is typically an elastomeric or rubber band.

[0007] As best illustrated in FIG. 2, the endoscope first end **42** is inserted into the receiving end **12** and through the throat **16**. The retainer **28** is then
15 placed over the throat **16** of the sheath **10**. The sleeve portion **18** is then inverted over the endoscope **40** to reveal the distal end **42** and the inner surface of the sleeve portion **18**, both of which are maintained as sterile.

[0008] While the retainer **28** serves to maintain the position of the sheath **10** on the endoscope **40**, it creates a raised portion having a height depicted at **26**.
20 This raised portion **26** must be taken into account when determining where the endoscope **40** or other medical instrument is to be inserted into the patient. The raised portion **26** can require a larger surgical opening in certain situations, or can create additional discomfort to a patient during insertion and removal into a patient's natural body opening. The retainer **28** also has a tendency to move along
25 the length of the endoscope **40** due to the interference between the raised portion **26** and the patient. It is also known that the application of such a retainer **28** can be difficult due to the required tensile strength and the small size thereof. The retainer **28** is, in certain situations, difficult to place while maintaining a sterile field including the distal end **42** of the endoscope **40** and the interior surface of the
30 sleeve portion **18** of the sheath **10**.

[0009] Prior art devices have normally involved the mounting of a fully extended sheath onto a carrier. In order to extend the probe into the entire length of the sheath, the medical technician or doctor will insert the probe through the sheath opening and slowly manipulate the tip of the probe such that it travels through the sheath length to its nose. This process can result in inadvertent contact with the wall of the sheath which will engage or become in direct contact with the patient.

[0010] Other devices have been developed to overcome these and similar problems associated with the manufacture and application of medical probe sheaths. Typical of the art are those devices disclosed in the following U.S. Patents:

	Patent No.	Inventor(s)	Issue Date
	3,308,940	T. Morris, Jr.	Mar. 14, 1967
	3,809,230	G. W. Poncy	May 7, 1974
15	3,847,280	G. W. Poncy	Nov. 12, 1974
	4,062,239	C. F. Fowler, <i>et al.</i>	Dec. 13, 1977
	4,164,285	H. P. Dorman	Aug. 14, 1979
	4,165,000	G. W. Poncy	Aug. 21, 1979
	4,197,944	D. G. Catlin	Apr. 15, 1980
20	4,241,828	P. A. Bourdelle <i>et al.</i>	Dec. 30, 1980
	4,614,442	G. W. Poncy	Sept. 30, 1986
	4,684,018	E. Järund	Aug. 4, 1987
	4,757,381	D. H. Cooper <i>et al.</i>	July 12, 1988
	4,823,949	H. Bala	Apr. 25, 1989
25	5,069,337	H. Bala	Dec. 3, 1991
	5,667,068	S. W. Weaver	Sept. 16, 1997
	5,769,224	R. Poncy <i>et al.</i>	June 23, 1998
	5,795,632	M. Buchalter	Aug. 18, 1998
	6,224,543	C. E. Gammons <i>et al.</i>	May 1, 2001

[0011] Of these devices, that disclosed by Weaver ('068) is a protective cover for use in the storage of an endoscope. The protective cover is a tubular member

defining a passageway running lengthwise through the member from end to end. A tapered portion is defined at one end for holding the endoscope in place as it is inserted into the passageway. A narrowed portion of the passageway is located at or near the distal end of the tubular member.

5 **[0012]** The '224 patent issued to R. Poncy *et al.*, discloses a sterile packaging system for a pipetter sheath. The packaging system comprises two inner thermoplastic strips sandwiched between two outer paper covers. The inner strips and outer covers are connected along a tear seal formed by an electromagnetic heat sealer. The tear seal is generally in the shape of a pipetter such that the sheath is
10 held in place by virtue of its conformity with the pipetter.

[0013] The remainder of the cited prior art disclose various embodiments of sheaths which are configured to cover the end of the probe. Specifically, the end of the sheath is closed. By having a closed end, the medical probe is retained within the sheath without risk of the sheath being pulled over the probe. While many
15 applications are conducive to the use of a probe whose distal end is enclosed within a sheath, there are many applications where the distal end of the medical instrument or probe must be unencumbered.

BRIEF SUMMARY OF THE INVENTION

[0014] The present invention is a cover for a medical probe or instrument.
20 The medical probe cover is provided for being applied to the distal end of a medical probe or instrument such as an endoscope and is adapted to be received over the end of the medical probe in such a manner as to not require the application of a retainer, whereby the patient is subjected to minimal discomfort. Once received on the medical probe, the distal end of the medical probe and the exposed portion of
25 the cover are disposed within a sterile field.

[0015] The cover generally defines an elongated tubular member having a first end and a second end. The cover defines a first panel member and a second panel member secured one to the other along their respective sides such that the first and second ends are open to define a tube. A throat is defined proximate the
30 first end and is adapted to closely receive the distal end of the medical probe. The

width of the throat is dimensioned to be less than half the circumference of the medical probe such that a tight fit is accomplished when the medical probe is inserted into the throat. The cover is fabricated from a material having elastomeric properties which allow it to stretch as the medical probe is inserted, and such that when stretched, the cover tends to return to its original shape thereby creating a tight bond between the cover and the medial probe to prevent removal of the cover.

[0016] The cover is tapered from the first end thereof to the throat to define a funnel configuration. Thus, as the medical probe is inserted into the cover, it is directed into and through the throat. The second end of the cover is then pulled to invert the cover up to the throat, thereby revealing the sterile inside surface of the cover and the distal end of the medical probe.

[0017] The first ends of each of the first and second panel members are defined with a double thickness of material, such as by folding over the respective panel member prior to heat sealing the panel members together as described above. The first panel member first end extends beyond the second panel member first end to define an extended portion. The extended portion of the first panel member provides a mechanism whereby the distal end of the medical probe is easily inserted into the first end of the cover. By placing the medical probe distal end on the extended portion, the first end of the cover is opened to allow insertion of the medical probe therein. The construction of the first ends, namely by folding to provide a double thickness, furthers the ease of opening the first end in the described manner. The second end of the cover is inverted to assist in the application of the cover of the medical probe.

[0018] To apply the cover of the present invention on a medical probe, the first end of the cover is engaged with the extension defined by the first panel member first end, thereby opening the first end of the cover. The medical probe is then inserted into the first end, through the throat and toward the second end of the cover. Once the throat is positioned on the medical probe at the desired location, the second end of the cover is inverted over the medical probe, thereby revealing the inside surface of the cover, which has heretofore remained untouched

and sterile. The medical probe, having the cover of the present invention applied thereto, is then prepared for use.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0019] The above-mentioned features of the invention will become more clearly understood from the following detailed description of the invention read together with the drawings in which:

FIG. 1 is a top plan view of a prior art sheath;

FIG. 2 is a top plan view of the prior art sheath of FIG. 1, shown being received on the end of a medical device, a retainer being received about the sheath to maintain the relative positions of the sheath and medical device;

FIG. 3 is a top plan view of a reinforced probe cover of the present invention;

FIG. 4 is an elevation view of the reinforced probe cover of the present invention, in cross-section taken along 4-4 of FIG. 3; and

FIG. 5 is a top plan view of the reinforced probe cover of the present invention, shown being received on a medical probe.

DETAILED DESCRIPTION OF THE INVENTION

[0020] A cover for a medical probe or instrument is disclosed. The medical probe cover of the present invention is illustrated generally at **110** in FIGS. 3-5. The medical probe cover, or cover **110**, is provided for being applied to the distal end **42** of a medical probe **40** or instrument such as an endoscope. The cover **110** is adapted to be received over the end **42** of the medical probe **40** in such a manner as to not require the application of a retainer **28** (see PRIOR ART FIGS. 1 and 2), whereby the patient is subjected to minimal discomfort. Further, the cover **110** is configured such that once received on the medical probe **40**, the distal end **42** thereof and the exposed portion of the cover **110** are disposed within a sterile field.

[0021] FIG. 3 illustrates a top plan view of the cover **110** of the present invention. The cover **110** generally defines an elongated tubular member having a first end **112** and a second end **120**, and a first side **122** and a second side **124**. The cover **110** defines a first panel member **126** and a second panel member **136** secured one to the other along their respective first sides **132,142** and their respective second sides **134,144**, whereby the first and second ends **112,120** are open to define a tube. As best illustrated in FIG. 4, the first and second panel members **126,136** each define first ends **128,138** and second ends **130,140**, respectively, which are disposed proximate each other prior to securement of the first and second panel members **126,136**. Referring again to FIG. 3, the first and second panel members **126,136** in the illustrated embodiment are secured one to the other using a conventional heat welding technique. However, it will be understood by those skilled in the art that other conventional techniques may be used.

[0022] A throat **116** is defined proximate the first end **112**. The throat **116** is adapted to closely receive the distal end **42** of the medical probe **40**. The width of the throat **116** is dimensioned to be less than half the circumference of the medical probe distal end **42** such that a tight fit is accomplished when the medical probe **40** is inserted into the throat **116**. To this extent, the cover **110** is fabricated from a material having elastomeric properties which allow it to stretch as the medical probe **40** is inserted. Further, the elastomeric properties of the cover **110** create a memory, whereby when stretched, the cover **110** tends to return to its original shape. Thus, when the medical probe **40** is inserted into the throat **116** of the cover **110** and the throat **116** is stretched, it has a tendency to return to its original shape and size, thereby creating a tight bond between the cover **110** and the medical probe **40** to prevent unselected removal of the cover **110**. In testing, a tensile strength of up to 0.96 lbs has been accomplished in the cover **110** of the present invention. As a result of the tensile strength accomplished in the present invention, as compared to the 0.35 lb tensile strength of the prior art covers **10** as discussed above, the need for a retainer has been obviated.

[0023] In the illustrated embodiment, the cover **110** is tapered from the first end **112** thereof to the throat **116** to define a funnel configuration **118**, whereby as

the medical probe **40** is inserted into the cover **110**, it is directed into and through the throat **116**. The second end **120** of the cover **110** is then pulled to invert the cover **110** up to the throat **116**, thereby revealing the sterile inside surface of the cover **110** and the distal end **42** of the medical probe **40**.

5 **[0024]** As best illustrated in FIG. 4, the first ends **128,138** of each of the first and second panel members **126,136** are defined with a double thickness of material. In the illustrated embodiment, each of the first and second panel member first ends **128,138** is defined by folding over the respective panel member **126,136** prior to heat sealing the panel members **126,136** together as described
10 above.

[0025] In the illustrated embodiment, the first panel member first end **128** extends beyond the second panel member first end **138** to define an extended portion **129**. The extended portion **129** of the first panel member **126** provides a mechanism whereby the distal end **42** of the medical probe **40** is easily inserted
15 into an opening **114** defined by the first end **112** of the cover **110**. By placing the medical probe distal end **42** on the extended portion **129**, the first end opening **114** of the cover **110** is opened to allow insertion of the medical probe **40** therein. The construction of the first ends **128,138**, namely by folding to provide a double thickness, furthers the ease of opening the first end opening **114** in the described
20 manner.

[0026] In the illustrated embodiment, the second end **120** of the cover **110** is inverted to assist in the application of the cover **110** on the medical probe **40**, as described below. However, it will be understood that the second end **120** may be disposed in various other configurations to assist in applying the cover **110** to a
25 medical probe **40**, to maintain the inner surface of the cover **110** as sterile until applied to the medical probe **40**, and, especially for covers **110** adapted for longer probes **40**, to reduce the overall length of the cover **110** prior to application on the probe **40**.

[0027] FIG. 5 best illustrates the application of the cover **110** of the present
30 invention. The first end **112** of the cover **110** is engaged with the extended portion **129** defined by the first panel member first end **128**, thereby opening the first end

opening 114 of the cover 110. The medical probe 40 is then inserted into the first end opening 114, through the throat 116 and toward the second end 120 of the cover 110. Once the throat 116 is positioned on the medical probe 40 at the desired location, the second end 120 of the cover 110 is inverted over the medical probe 40, thereby revealing the inside surface of the cover 110, which has heretofore remained untouched and sterile. The medical probe 40, having the cover 110 of the present invention applied thereto, is then prepared for use.

[0028] From the foregoing description, it will be recognized by those skilled in the art that a medical probe cover adapted to be received on a medical probe has been provided. The medical probe cover is provided for being applied to the distal end of a medical probe or instrument such as an endoscope in such a manner as to not require the application of a retainer, whereby the patient is subjected to minimal discomfort. The cover is configured such that once received on the medical probe, the distal end of the medical probe and the exposed portion of the cover are disposed within a sterile field

[0029] While the present invention has been illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and methods, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of applicant's general inventive concept.